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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,215	01/20/2004	Bernard Querleux	006459.00001	6431

22907 7590 10/28/2009

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EXAMINER	
CWERN, JONATHAN	
ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
10/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,215	QUERLEUX ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 11-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 31-34 are objected to because of the following informalities:

Claims 31, 32, and 33 are improper dependent claims, as they appear to be written as independent method claims; however they refer to "the apparatus according to claim 1". These claims are thus improper dependent claims, as they fail the infringement test, and should be rewritten in proper independent form. Reference to claim 1 should be removed. See MPEP 608.01(n) III.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-9, 11-17, 24, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Krause et al. (US 5545124).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose a coupling member between the probe and skin.

Krause et al. disclose a method for alleviating the sensation of pain. As seen in Figure 1, an acoustic coupler in a disc shape can be disposed between the skin and the probe (column 5, line 64-column 6, line 7).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the probe of Fink et al. to use an acoustic coupler as taught by Krause et al. The use of an acoustic coupler in ultrasound systems is well known in the art. There are a variety of benefits provided by such a coupler, including establishing a stable connection between the skin and probe for ultrasound waves to propagate, or reducing the intensity of shockwaves. It would further be an obvious design choice to one of ordinary skill in the art, to select the size/thickness of the coupling member to be any size/thickness, which would enable the user to observe the desired portion of the patient's body via the focal length and depth. Furthermore, it would be an obvious design choice to modify the device of Fink et al. to incorporate the probe and vibrator into a frame. A frame, or housing, can allow for the parts of the device to be held in relation to each other, and to provide a level of support and protection for the components.

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Krause et al. (US 5545124) as applied to claim 1 above, and further in view of Liu et al. (US 2004/0064050).

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue

mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data. Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Fink et al. to analyze the skin, as taught by Liu et al. While Fink et al. do not specifically state that the skin is analyzed using their device, one of ordinary skill in the art would recognize that such as device can be used to analyze a variety of different portions of the body, not only those discussed by Fink et al. It would be obvious to do so as any part of the body may require a diagnosis. While Liu et al. do not specifically mention determining the degree of aging of the skin, Liu et al. do compare values taken at different points in time, to determine if any changes have taken place in the skin. This can be considered an analysis of aging.

Also, Fink et al. disclose that 1000 to 100,000 shots per second are fired by the ultrasound probe, and that the signals are sampled and digitized in real time after each shot. It would be an obvious design choice to one of ordinary skill in the art to select how often the probe stores/picks up the signals.

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Krause et al. (US 5545124) and Liu et al. (US 2004/0064050).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000 Hz. Fink et al. fail to disclose analyzing the skin.

Krause et al. disclose a method for alleviating the sensation of pain. As seen in Figure 1, an acoustic coupler in a disc shape can be disposed between the skin and the probe (column 5, line 64-column 6, line 7).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the probe of Fink et al. to use an acoustic coupler as taught by Krause et al. The use of an acoustic coupler in ultrasound systems is well known in the art. There are a variety of benefits provided by such a coupler, including

establishing a stable connection between the skin and probe for ultrasound waves to propagate, or reducing the intensity of shockwaves. It would further be an obvious design choice to one of ordinary skill in the art, to select the size/thickness of the coupling member to be any size/thickness, which would enable the user to observe the desired portion of the patient's body via the focal length and depth. Furthermore, it would be an obvious design choice to modify the device of Fink et al. to incorporate the probe and vibrator into a frame. A frame, or housing, can allow for the parts of the device to be held in relation to each other, and to provide a level of support and protection for the components.

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data. Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the system of Fink et al. to analyze the skin, as taught by Liu et al. While Fink et al. do not specifically state that the skin is analyzed using their device, one of ordinary skill in the art would recognize that such as device can be used to analyze a variety of different portions of the body, not only those discussed by Fink et al. It would be obvious to do so as any part of the body may require a diagnosis. While Liu et al. do not specifically mention determining the degree

of aging of the skin, Liu et al. do compare values taken at different points in time, to determine if any changes have taken place in the skin. This can be considered an analysis of aging. In any case, it would be an obvious to use the device to analyze a variety of different properties relating to the skin, depending on the user's preference.

Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fink et al. (US 6770033) in view of Krause et al. (US 5545124), Liu et al. (US 2004/0064050), and Popovic et al. (US 5115808).

Fink et al. disclose an imaging method and device using shearing waves. A vibrator is arranged against the skin of a patient, to generate shear waves into the viscoelastic medium. An ultrasound probe is used to observe the propagation of the shear wave. The probe can be arranged in a variety of ways, such as on the same side of the medium as the vibrator, on the opposite side, or any other position (column 4, line 66-column 5, line 67). The probe is arranged along an axis, and the vibrator is arranged in such a way that it can be considered "from a surface of the apparatus in contact with a region of the skin extending around the axis". As seen in Figure 1, the entire skin surface can be considered the "region of the skin", which extends around the ultrasound probe, and therefore the vibrator is in contact with a region of the skin extending around the axis. As seen in Figure 2, the vibrator, which is annular shaped, and probe can be arranged in such a way that the probe extends through a central bore in the vibrator. The probe is arranged to emit and receive ultrasound waves in a frequency range of 1 to 100 MHz. The vibrator can emit a pulse with a frequency in the range of 20 to 5000

Hz. Fink et al. fail to disclose analyzing the skin and using the data to determine the effects of a treatment.

Krause et al. disclose a method for alleviating the sensation of pain. As seen in Figure 1, an acoustic coupler in a disc shape can be disposed between the skin and the probe (column 5, line 64-column 6, line 7).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the probe of Fink et al. to use an acoustic coupler as taught by Krause et al. The use of an acoustic coupler in ultrasound systems is well known in the art. There are a variety of benefits provided by such a coupler, including establishing a stable connection between the skin and probe for ultrasound waves to propagate, or reducing the intensity of shockwaves. It would further be an obvious design choice to one of ordinary skill in the art, to select the size/thickness of the coupling member to be any size/thickness, which would enable the user to observe the desired portion of the patient's body via the focal length and depth. Furthermore, it would be an obvious design choice to modify the device of Fink et al. to incorporate the probe and vibrator into a frame. A frame, or housing, can allow for the parts of the device to be held in relation to each other, and to provide a level of support and protection for the components.

Liu et al. disclose a system and method for screening tissue. Liu et al. teach that the tissue can be skin. Different areas of the skin will yield different data, such as tissue mechanical properties, based on their state of healthiness. A tissue model can store information concerning for example, tissue elasticity, to compare with the obtained data.

Data can also be acquired over time, and old data can be compared to new data to see if any changes in the skin have taken place over time ([0104]-[0106) and [0123]-[0126]).

Popovic et al. disclose a method and device for noninvasive acoustic testing of elasticity of soft biological tissues. Popovic et al. teach that the elasticity of the skin can be measured before and after a treatment, to determine the effects of the treatment (column 7, lines 10-35).

It would have been obvious to one of ordinary skill in the art, to have used the system of Fink et al. in a variety of different ways, such as for analyzing skin as taught by Liu et al. The use of analysis methods for a variety of different reasons are well known in the art, such as diagnosis to determine which type of treatment, or what the most effective treatment will be. Or diagnosis to determine the effects of a treatment, to determine if the treatment is successful or if more treatment is necessary, or a different type of treatment. Popovic et al. provides several examples, such as analyzing the skin before and after a treatment to determine its effectiveness, diagnosing skin pathologies, or differentiating between normal and pathological tissue during surgical operations. It would be obvious to use the system of Fink et al. for any diagnosis purposes.

Response to Arguments

Applicant's arguments filed 2/25/09 have been fully considered but they are not persuasive.

In regards to applicant's arguments regarding modifying the device of Fink et al. to include an acoustic coupler, examiner respectfully disagrees.

The use of an acoustic coupling medium between the ultrasound probe and the body is an old and well known expedient in the art. One of ordinary skill in the art designing or using an ultrasound probe would be well aware of the obvious benefits such an acoustic coupler could provide, and could select to use one if desired. This would be an obvious design choice. Acoustic couplers come in a variety of shapes, sizes, and designs and one can be selected which would operate effectively with the device of Fink et al. Krause et al. provide one such example of an acoustic coupler.

Furthermore, applicant argues that if such an acoustic coupler would be used, no surface of the speaker would be in contact with the acoustic coupler, examiner respectfully disagrees. The examiner would point out Figure 1 in applicant's disclosure, which shows the vibrator 4, probe 5, and coupling member 23. This is a similar arrangement to the device of Fink et al. in Figure 2. The vibrator is in contact with the acoustic coupler (which would be included between the probe and skin as modified by Krause et al.) via other parts of the device, as they are all connected. Similarly, applicant argues that the probe surface and contact surface are not coplanar. However, the arrangement is similar to that of applicant's own invention. They are co-planar in that applicant has not specified any particular plane, and there will exist some plane in which both lie. Even so, as the arrangement of Fink et al. is so similar to applicant's arrangement as shown in Figure 1 of applicant's disclosure, the examiner is unconvinced by these arguments that try to distinguish between the two.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

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